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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,379	01/23/2004	Albert Zorko Abram	021706-000420US	7565

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,379

Applicant(s)

ABRAM ET AL

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12, 14-62 and 64 is/are pending in the application.
4a) Of the above claim(s) 7, 10-12, 39-62 and 64 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6, 8 and 14-38 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/04, 4/04, 4/05
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

RESTRICTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 10-12 and 14-38, drawn to a composition comprising a quick-break foaming agent and active agents, classified in class 424, subclass 45.
- II. Claims 39-62, drawn to a method of treating acne, classified in class 514, subclass 859.
- III. Claim 64, drawn to a composition comprising clindamycin phosphate and benzoyl peroxide, water and propellant, classified in class 424, subclass 78.07 or 45.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case acne can be treated by various other active agents and dosage forms, and composition of claim 1 can be used in treating various other disorders.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to compositions comprising different components. For example claim 1 comprises a quick-break foaming agent and an active agent. The scope of active agent is very broad, while the requirements of the foaming agent are specific. Claim 64 is drawn to a composition that does not contain the quick-break foaming agents, while limiting the active agents to clindamycin and benzoyl peroxide.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

ELECTION

Claims 7, 8, 10-12 and 15 are generic to a plurality of disclosed patentably distinct species comprising various active agent combinations (claims 7 and 8) and various ethanol:water ratios (claims 10-12 and 15). Applicant is required under 35

U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

During a telephone conversation with Mr. Joseph Snyder on 4/22/05 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-8, 10-12, 14-38. Applicant also elected the combination of claim 8 and the ratio of claim 15. Affirmation of this election **must** be made by applicant in replying to this Office action. Claims 7, 10-12, 39-62 and 64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites the limitation "does not contain C1-C6 alcohol" in composition of claim 1. There is insufficient antecedent basis for this limitation in the claim.

Composition of claim 1 is **positively** reciting the existence of a C1-C6 alcohol in the formulation. Thus dependent claim 38 can not appropriately exclude a component that is already present in the formulation recited in claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5 and 14-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones et al (20030118511 A).

Jones et al teach corticosteroid- containing pharmaceutical compositions comprising a corticosteroid, a quick-break foaming agent, a propellant and a buffering agent. The said composition is applied to the skin site as a foam, which is a thermophobic quick-break foam (see [0006] and [0007]). The quick-break foaming agent comprises an aliphatic alcohol, in an amount of from 40-90%, water in an amount of

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from 10-40%, at least one fatty alcohol in an amount of from 0.5 to 10% and a surface active agent in an amount of from 0.1 to 15% w/w (see [0008]).

Jones also discloses that the aliphatic alcohol may be selected from ethanol, methanol, isopropanol, etc, or mixtures thereof (see [0014]). The fatty alcohol may be selected from cetyl alcohol, stearyl alcohol, or mixtures of the two, known as octadecan-1-ol (see [0013]). The surface active agent may be selected from ethoxylated sorbitan stearate, palmitate, oleate or mixtures thereof. Suitable surfactant is polysorbate 60 ([0015]). The propellant may be selected from butane, propane, ethane, etc, which is present in an amount of 3-30 or preferably from 3-5% w/w (see [0016]). The composition may contain a buffering agent and the desirable pH level is from 3.0 to 6.0, and most preferably from 4.0 to 5.0 ([0021]). The composition may also comprise a humectant such as propylene glycol, glycerine, sorbitol, etc, present in an amount of from 0.5 to 3.0% w/w (see [0017]).

Jones et al teach that corticosteroids, or a mixture of corticosteroids, are present in the formulation from about 0.01 to 1.0% w/w (see [0018]-[0020] and claim 8). It is also disclosed that in use, the composition is sprayed, producing a semi-solid (i.e. foam or mousse) that is suitable for the topical application to skin or scalp. On application, heat from the skin causes the foam to break down to liquid form (see [0025]). Jones exemplifies a formulation in a table disclosed under section [0028], which discloses amounts of each ingredient. For example the formulation comprises 57.79% ethanol and 33.69% water. Thus the ratio of ethanol : water is 1.7:1, the same as the requirements of instant claim 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-4, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al (20030118511 A1) in view of Popp (20040043946 A1).

Jones et al, discussed above, discloses a formulation comprising a quick-break foaming agent, a propellant and corticosteroid as the active agent. Jones et al does not disclose other active agent suitable for inclusion in the said foam formulation.

Popp discloses a topical compositions comprising a storage-stable mixture of benzoyl peroxide and clindamycin or a pharmaceutically acceptable salt or esters thereof, in a suitable carrier and a method of using the said formulation. The said

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formulation has a pH value of 4.5 to about 5 (see [0016]-[0017] and [0020]). The formulation preferably comprises clindamycin phosphate in an amount of from 0.9 to 2.5% by weight of the total composition ([0039] and [0040]).

Popp discloses that the benzoyl peroxide as well as the final composition may be in the form of a foam (see [0046]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the formulations of Jones et al of a quick-break foam comprising an active agent, corticosteroid, with the combination of acne treating agents such as clindamycin phosphate and benzoyl peroxide in a foam dosage form, as taught by Popp with a reasonable expectations of successfully preparing an efficient and stable foam for treating skin disorders such as acne.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lisboa et al (5,679,324).

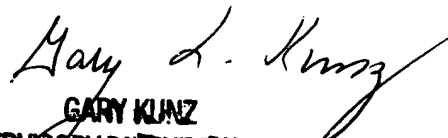
Lisboa et al teach an aerosol foamable composition which comprises a fast breaking foam, comprising a surfactant, a thickener and a propellant. The formulation may contain active agents such as benzoyl peroxide and clindamycin.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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May 04, 2005